

1 **UNITED STATES DISTRICT COURT**
2 **DISTRICT OF NEVADA**

3 BARBARA HEINRICH and GREGORY
4 HEINRICH,

5 Plaintiffs

6 v.

7 ETHICON, INC.; ETHICON LLC; and
8 JOHNSON & JOHNSON,

9 Defendants

Case No.: 2:20-cv-00166-APG-VCF

**Order Granting in Part Defendants’
Motion in Limine No. 5**

[ECF No. 133]

10 This case is one of many thousands of cases that were joined in multidistrict litigation
(MDL) in the United States District Court for the Southern District of West Virginia. The case
11 was transferred to this court for trial in January 2020. ECF No. 69. The defendants filed a
12 motion *in limine* seeking to exclude from trial various internal company documents and emails as
13 irrelevant and unfairly prejudicial.

14 **A. Emails**

15 The defendants seek to exclude three emails they contend are irrelevant and unfairly
16 prejudicial. The first email refers to a patient’s complaint about erosion related to a TVT
17 product. ECF No. 133-1 at 3. The email states that the patient’s husband said that “sex is like
18 screwing a wire brush.” *Id.* Dr. Weisberg wrote back that he “never tried the wire brush thing so
19 I won’t comment.” *Id.* at 2. In the second email, in response to a physician report of seeing blue
20 particles falling off the mesh of two TVT products (neither of which is the TVT-S), Dan Smith
21 from Ethicon’s research and development division stated that surgeons should be told
22 “UPFRONT that they will see BLUE shit and it is OK.” ECF No. 133-2 at 2. The third email
23 chain involves a discussion of follow-up questions for Prolift surgical patients, including

1 questions about sexual experiences. ECF No. 133-3. One Ethicon team member stated that he
2 “would not like for my wife to undergo this procedure.” *Id.* at 4. The plaintiffs respond that they
3 now have no intention of using these exhibits and do not oppose this portion of the defendants’
4 motion.

5 Given the plaintiffs’ response, it is unclear why this issue was not resolved at the meet
6 and confer. But because the plaintiffs no longer oppose this portion of the motion, I grant it. LR
7 7-2(d).

8 **B. Dr. Eberhard’s Letter**

9 The defendants seek to exclude an October 2004 letter from German surgeon Dr.
10 Eberhard regarding a demo unit. The defendants argue the letter is irrelevant because the demo
11 unit was not a TVT-S, and there is no evidence of how the unit was handled so any reference to
12 the unit “crumbling” is not relevant and is unfairly prejudicial. They also contend the letter is
13 inadmissible hearsay. The plaintiffs respond that they now have no intention of using this
14 exhibit and do not oppose this portion of the defendants’ motion.

15 Again, it is unclear why this issue was not resolved at the meet and confer meeting. But
16 because the plaintiffs no longer oppose this portion of the motion, I grant it. LR 7-2(d).

17 **C. October 2002 Emails Regarding Prolene**

18 The defendants seek to exclude an October 2002 email chain between Dr. Axel Arnaud
19 and Dr. Martin Weisberg about Prolene Soft mesh because that mesh is not at issue here and any
20 reference in the letter to being “more elusive” about warnings regarding fistulas and erosions
21 would unfairly prejudice the defendants.

22 The plaintiffs respond that the email may be used to impeach Dr. Arnaud, although they
23 do not explain how. They also assert that the email chain is relevant to whether the defendants

1 understated the risks of Prolene Soft mesh that Dr. Shlomo Raz used to implant a spiral sling in
2 Barbara Heinrich in 2011. The plaintiffs note that the defendants intend to allege Dr. Raz's
3 spiral sling surgery caused Barbara Heinrich's devastated urethra. The plaintiffs thus contend
4 that Dr. Raz's use of Prolene Soft and any warnings the defendants provided (or failed to
5 provide) may be relevant in this case.

6 I deny this portion of the defendants' motion because the parties have not provided me
7 with sufficient information to make an informed decision. Given that the parties were required
8 to confer prior to the defendants filing their motion, the defendants should have anticipated the
9 plaintiffs' arguments. However, they do not address impeachment or the anticipated attack on
10 Dr. Raz's decision to use the mesh for a spiral sling. The plaintiffs, on the other hand, give me
11 no information about Dr. Arnaud's proposed testimony or how this email would impeach him.

12 I therefore deny this portion of the defendants' motion, without prejudice to raising it in
13 another motion *in limine* that is properly supported. If this email is not going to be introduced in
14 the first-phase trial, then the motion *in limine* should not be filed until that portion of the case is
15 concluded because it may become moot if the jury determines the plaintiffs' claims are untimely.

16 **D. December 2008 and January 2009 Emails Involving Dr. Chen**

17 The defendants seek to exclude emails from December 2008 and January 2009 involving
18 Dr. Chen. The defendants argue that the emails post-date Barbara Heinrich's implantation, so
19 they are irrelevant. They also argue that the emails post-date a public advisory issued by the
20 FDA, so physicians already knew about the concerns Dr. Chen was expressing. The defendants
21 assert that a manufacturer has no duty to warn of risks already known, so they had no duty to add
22 anything to the TVT-S's instructions for use (IFU). Finally, they contend these emails should be
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1 excluded under Federal Rule of Evidence 407 because any changes to the IFU after Barbara
2 Heinrich's implantation would be an inadmissible subsequent remedial measure.

3 The plaintiffs respond that the TVT-S's IFU was not changed, and thus there is no
4 concern about a subsequent remedial measure under Rule 407. The plaintiffs argue the evidence
5 is relevant to the defendants' state of mind before Barbara Heinrich's implantation regarding
6 why the TVT-S's IFU was not updated even though the defendants had gained further
7 knowledge about problems with the implantation method associated with this product. The
8 plaintiffs contend the emails are also relevant as to why the plaintiffs were not on inquiry notice
9 that the TVT-S was defective because the defendants did not change the IFU that would have
10 informed Barbara Heinrich and her physicians about potential defects. The plaintiffs contend
11 these emails are also relevant to their failure to warn claim because the defendants subsequently
12 represented to Dr. Hsieh that complications were already adequately addressed in the IFU,
13 whereas Dr. Chen was suggesting the IFU was inadequate.

14 In the December 2008 email, Dr. Chen responded to a patient complaint that the patient
15 did not receive informed consent. ECF No. 133-9 at 2. Dr. Chen stated that the patient had
16 received a "risk-benefit consultation before her surgery in 2005" and she was "given the most
17 accurate consent for the potential adverse reaction[s] known in 2005." *Id.* Dr. Chen then stated
18 that "[h]owever, we are in 2008 now and there are two more TVT family products (TVTO and
19 TVTS) on the market. Our post-market knowledge with these products are much more than what
20 we have in the IFUs of all three types of TVTs" *Id.* Dr. Chen suggested that the IFU for the
21 TVT-S (along with two other TVT products) be updated, "particularly in the area of 'Potential
22 Adverse Reactions.'" *Id.* Dr. Chen noted that the FDA recently highlighted the issue of pre-
23 operative consent, and "[o]ne of the paths for a better pre-operative consent is to provide an

1 updated IFU to the operating physicians that reflect[s] the current knowledge of the
2 manufacturer[] on the potential adverse reactions.” *Id.*

3 In January 2009, Chen suggested that the IFU “spell[] out that Transitory local irritation
4 at the wound site and a transitory foreign body response to the tape may occur,” and that this
5 response “could result in tape extrusion, tape erosion, fistula formation or inflammation.” ECF
6 No. 133-10. She also stated that “from what [she sees] each day, these patient experiences are
7 not ‘transitory’ at all.” *Id.*

8 The defendants have presented no evidence that the TVT-S’s IFU was changed or
9 updated, so Rule 407 does not apply. Dr. Chen’s emails are relevant to the issue of when a
10 reasonably diligent plaintiff, either on her own or through information disclosed to her by her
11 physician, could or should have discovered that the TVT-S was defective and causing her post-
12 surgery injuries as opposed to normal complications from this type of treatment. The IFU is part
13 of the mix of information available to Barbara Heinrich and her physicians. The emails are also
14 relevant to the plaintiffs’ failure to warn claim to the extent they suggest the defendants were on
15 notice that the IFU did not adequately inform physicians of potential adverse reactions that were
16 more than transitory. A jury will have to resolve whether the complications to which Dr. Chen
17 was referring were commonly known to physicians such that no further warning was needed. I
18 therefore deny this portion of the defendants’ motion.

19 **E. Top Ten Presentation**

20 The defendants seek to exclude a PowerPoint presentation entitled “Top Ten Reason[s] to
21 Pursue . . . GYNECARE TVT Obturator System.” The defendants argue the presentation was
22 intended as humor for Ethicon sales personnel and not as a substantive presentation. The
23 defendants argue the presentation is irrelevant and unfairly prejudicial.

1 The Top Ten Reasons PowerPoint presentation was prepared in part and presented by
2 Brian Luscombe. ECF Nos. 133-11; 133-12 at 4. Luscombe intended the list to be a humorous
3 ice breaker for Ethicon sales personnel and it was based on David Letterman's top ten lists. ECF
4 No. 133-12 at 4. The plaintiffs seek to include only three items off the list, so I address only
5 those.

6 *1. Item 6 Regarding Dr. Shlomo Raz*

7 Item 6 of the top ten lists states: "When Shlomo Raz tries to make a knock-off, it will
8 cost him at *least* \$25." ECF No. 133-11 at 3 (emphasis in original). The plaintiffs contend the
9 reference to Dr. Raz shows a "company-wide prejudice" against Dr. Raz and helps to explain
10 why the defendants and their experts are attacking Dr. Raz's use of the defendants' own mesh in
11 performing the spiral sling surgery on Barbara Heinrich. The plaintiffs contend the defendants
12 are biased against Dr. Raz because, although he uses the defendants' mesh, he cuts his own
13 rather than using the defendants' devices, thereby paying substantially less money to the
14 defendants.

15 The defendants do not address this proposed relevancy of the evidence in their motion.
16 They also do not explain why this item's probative value is substantially outweighed by the
17 danger of unfair prejudice. Instead, they argue generally about the top ten list as a whole. Given
18 that the parties were required to confer prior to the defendants filing their motion, the defendants
19 should have anticipated the plaintiffs' arguments, but they did not address them in their motion.
20 I therefore deny the defendants' motion as to this portion of the top ten list.

21 *2. Item 5 Regarding the Hammock Shape*

22 Item 5 of the list states: "The hammock shape of the sling may result in less obstructive
23 symptoms, since it is harder to over-compress the urethra with the obturator sling." *Id.* The

1 plaintiffs argue this is relevant because the defendants' attempts to use the hammock method for
2 the TVT-S was a failure compared to the TVT-O, as was the "U" implant method until the
3 defendants changed the implantation method. The plaintiffs argue this item is probative of the
4 defendants' knowledge that the TVT-O was superior to the TVT-S but they nevertheless
5 continued to push the TVT-S for financial reasons.

6 The defendants do not address the proposed relevancy of the evidence in their motion.
7 They also do not explain why this item's probative value is substantially outweighed by the
8 danger of unfair prejudice. Instead, they argue generally about the list as a whole. Given that
9 the parties were required to confer prior to the defendants filing their motion, the defendants
10 should have anticipated the plaintiffs' arguments, but they did not address them in their motion.
11 I therefore deny the defendants' motion as to this portion of the top ten list.

12 *3. Item #3 Regarding De Novo Urgency*

13 Item 3 of the list states: "de novo urgency—you know, when the patient hasn't had
14 urgency prior to surgery, but then gets it as a result of the surgery? Some hypothesize that it may
15 be less." *Id.* The plaintiffs argue this is relevant because Barbara Heinrich had urgency
16 complications caused by the TVT-S implantation method, which would not have happened with
17 the TVT-O.

18 The defendants do not address the proposed relevancy of the evidence in their motion.
19 They also do not explain why this item's probative value is substantially outweighed by the
20 danger of unfair prejudice. Instead, they argue only generally about the list as a whole. Given
21 that the parties were required to confer prior to the defendants filing their motion, the defendants
22 should have anticipated the plaintiffs' arguments, but they did not address them. I therefore deny
23 the defendants' motion as to this portion of the list.

1 **F. PA Consulting Group Report**

2 The defendants seek to exclude a 2011 report by PA Consulting Group entitled
3 “Investigating Mesh Erosion in Pelvic Floor Repair.” The defendants argue the report is hearsay,
4 irrelevant, and unfairly prejudicial because it is an out-of-court statement by a consulting
5 company that discusses many products and issues not at issue in this case. The plaintiffs respond
6 that Judge Goodwin has ruled in the MDL that the report is relevant and admissible because the
7 report discusses general mesh erosion and mesh erosion rates, and so is probative of the
8 plaintiffs’ claims. The plaintiffs argue the report will be used to impeach the defendants’
9 witnesses, whom the plaintiffs anticipate will testify the TVT-S mesh did not erode, and for non-
10 hearsay purposes such as notice and knowledge.

11 Judge Goodwin denied a similar motion and the defendants’ motion does not persuade
12 me to reach a different conclusion. As Judge Goodwin stated, the defendants’ argument that the
13 report refers to mesh for treating pelvic organ prolapse and not stress urinary incontinence is
14 “misleading.” *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2014
15 WL 505234, at *11 (S.D.W. Va. Feb. 5, 2014). “While Ethicon argues that the report was
16 written only to address issues related to pelvic organ prolapse, the report itself states that Ethicon
17 asked PA Consulting Group ‘to conduct a broad analysis of the problem of mesh erosion[.]’” *Id.*
18 (quoting the report). “The report does not state anywhere that it was examining erosion only as it
19 relates to pelvic organ prolapse; rather, it discusses mesh erosion generally, in line with the broad
20 analysis requested by Ethicon.” *Id.* “Although the overall purpose of the report may have been
21 to aid Ethicon in developing a next-generation device for pelvic organ prolapse, its discussion of
22 general mesh erosion is relevant to the plaintiffs’ claims. It also contains erosion rates of mesh,
23 which have probative value.” *Id.* The report therefore has probative value and the defendants

1 have not shown that the probative value is substantially outweighed by the danger of unfair
2 prejudice.

3 The defendants do not address the plaintiffs' proposed non-hearsay uses for the report.
4 Given that the parties were required to confer prior to the defendants filing their motion, the
5 defendants should have anticipated the plaintiffs' arguments, but they did not address them in
6 their motion. I therefore deny the defendants' motion as to the PA Consulting Group report.

7 **G. Payments Under the 1997 License Agreement**

8 The defendants seek to exclude evidence that Dr. Ulmsten may have received under a
9 1997 License and Supply Agreement. *See* ECF No. 133-15 (License and Supply Agreement).
10 The defendants argue the plaintiffs will attempt to show that milestone payments Dr. Ulmsten
11 received were for favorable results, but they contend there is no evidence Dr. Ulmsten did
12 anything unethical and his results have been repeated by others since then. The plaintiffs
13 respond that Judge Goodwin has already ruled this evidence admissible because Dr. Ulmsten's
14 financial interest is probative of negligence, punitive damages, and bias.

15 Judge Goodwin previously has concluded that "evidence about Professor Ulmsten's
16 financial interest is probative of the negligence and punitive damages claim and is not unduly
17 prejudicial." *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2014
18 WL 505234, at *7 (S.D.W. Va. Feb. 5, 2014). The defendants' motion does not persuade me
19 that Judge Goodwin was incorrect. The defendants are free to argue to the jury that the payments
20 Dr. Ulmsten received had no impact on his testing or, if he testifies, his credibility. Whether a
21 witness's financial interest impacts his credibility is a matter for the jury to resolve. *See United*
22 *States v. Abel*, 469 U.S. 45, 52 (1984) ("Proof of bias is almost always relevant because the jury,
23 as finder of fact and weigher of credibility, has historically been entitled to assess all evidence

1 which might bear on the accuracy and truth of a witness' testimony.''). I therefore deny the
2 defendants' motion as to the payments under the licensing agreement.

3 **H. Conclusion**

4 I THEREFORE ORDER that the defendants' motion in limine No. 5 (**ECF No. 133**) is
5 **GRANTED in part.**

6 DATED this 1st day of November, 2021.

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9 ANDREW P. GORDON
10 UNITED STATES DISTRICT JUDGE
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